

EC DECLARATION OF CONFORMITYAccording to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

Document No.: DOC-W812(1)-01

Version: 00

Manufacturer: **Guangzhou Wondfo Biotech Co., Ltd.**
Address: No.8, Lizhishan Road, Science City, Luogang District,
510663, Guangzhou, P.R. China

EC Authorised Representative: Qarad BV
Address: Cipalstraat 3, 2440 Geel, Belgium

***In Vitro* Diagnostic Medical Device(s):**

Product Name: Finecare™ D-Dimer Control
Cat. No.: W812
IVDD Classification: Other, for professional use

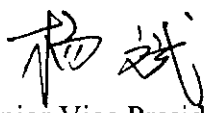
This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Regulation (EC) No 1272/2008.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 18113-1:2011	EN 13612:2002
EN ISO 14971:2019	EN ISO 18113-2:2011	EN 13641:2002
EN ISO 23640:2015	EN ISO 15223-1:2016	EN 62366-1:2015

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: **Annex III, excluding 6**

Notified Body (if consulted): Not Applicable
Address: /
EC Certificate(s): /
Expiry date of the Certificate(s): /

Signature of manufacturer
(Name and function):  Bin Yang, Senior Vice President of Regulatory Affairs
Place and date of issue: Guangzhou, P.R. China,
April 20, 2022

EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

No.: DOC-W211(1)-01

Version: 00

Manufacturer: Guangzhou Wondfo Biotech Co., Ltd.
Address: No.8, Lizhishan Road, Science City, Luogang District,
510663, Guangzhou, P.R. China

EC Authorised Representative: Qarad BV
Address: Ciplastraat 3, 2440 Geel, Belgium

In Vitro Diagnostic Medical Device(s):

Product Name: Finecare™ D-Dimer Rapid Quantitative Test
Cat. No.: W211
IVDD Classification: Other, for professional use

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Regulation (EC) No 1272/2008.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 18113-1:2011	EN 13612:2002
EN ISO 14971:2019	EN ISO 18113-2:2011	EN 13641:2002
EN ISO 23640:2015	EN ISO 15223-1:2016	EN 62366-1:2015
EN ISO 17511:2003		

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: **Annex III, excluding 6**

Notified Body (if consulted): Not Applicable
Address: /
EC Certificate(s): /
Expiry date of the Certificate(s): /

Signature of manufacturer 
(Name and function): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,
March 11, 2022



EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

Manufacturer: Guangzhou Wondfo Biotech Co., Ltd.
Address: No.8, Lizhishan Road, Science City, Luogang District,
510663, Guangzhou, P.R. China

EU Authorised Representative: Qarad BV
Address: Cipalstraat 3, 2440 Geel, Belgium

***In Vitro* Diagnostic Medical Device(s):**

Product Name: Finecare™ FIA Meter II Plus SE
Cat. No.: FS-114
IVDD Classification: Other, for professional use

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 14971:2019	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 18113-1:2011	EN ISO 18113-3:2011
EN 62304:2006	EN 62366-1: 2015	EN 61010-1: 2010+A1:2019
EN 61010-2-101:2017	EN 62133-2:2017	EN 61326-1:2013
EN 61326-2-6:2013	EN IEC 62311:2020	EN 61010-2-081:2015
ETSI EN 301 489-17	ETSI EN 300 328	ETSI EN 301 489-1
V3.2.4(2020-09)	V2.2.2(2019-07)	V2.2.3(2019-11)

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: **Annex III, excluding 6**

Notified Body (if consulted): Not applicable
Address: /
EC Certificate(s): /
Expiry date of the Certificate(s): /

Signature of manufacturer (Name and function):

Lingfang Huang, Vice President of Regulatory Affairs

Issue date: 2021-08-20